

FEB - 6 2004

K033703

**510(k) SUMMARY**

**DENTSPLY**

NAME & ADDRESS:

**DENTSPLY International**  
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CONTACT: P. Jeffery Lehn

DATE PREPARED: November 21, 2003

TRADE OR PROPRIETARY NAME: IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE

CLASSIFICATION NAME: Bracket adhesive and tooth conditioner resin (872.3750)

PREDICATE DEVICES: High-Q-Bond Adhesive Resin Cement K933766

DEVICE DESCRIPTION: The IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE system is a two-part light-cure system: an adhesive and a primer. A tooth conditioner is available if desired for the highest stress bonding cases.

IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE bonds metal, plastic, and ceramic orthodontic brackets to natural teeth, acrylic teeth, porcelain crowns, or amalgams.

The adhesive is packaged in syringes. No mixing is necessary. The primer is packaged in unit dose, self-dispensing capsules.

INTENDED USE: IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE is indicated for bonding of orthodontic brackets to natural and artificial tooth surfaces.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE have been used in legally marketed devices or were found safe for dental use.

We believe that the prior use of the components of the IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE in legally marketed devices, the performance data provided, and the similarity of the predicate to the new device support the safety and effectiveness of the IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE for the intended uses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. P. Jeffery Lehn  
Director of Corporate Compliance & Regulatory Affairs  
DENTSPLY International  
570 West College Avenue  
P.O. Box 872  
York, Pennsylvania 17405-0872

Re: K033703  
Trade/Device Name: Ideal®1 Orthodontic Bracket Adhesive  
Regulation Number: 872.3750  
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner  
Regulatory Class: II  
Product Code: DYH  
Dated: November 21, 2003  
Received: November 25, 2003

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph., D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure


## INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e))

510(K) Number (if known):

Device Name: **IDEAL® 1 ORTHODONTIC BRACKET ADHESIVE**Indications for Use:

Bonding of orthodontic brackets to natural and artificial tooth surfaces

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices  
510(k) Number: K033703

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)